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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/361,542 07/27/99 DOBROZSI

D 7247M

EXAMINER
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HM12/0908

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PULLIAM, A	
ART UNIT	PAPER NUMBER

1615

DATE MAILED:

09/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademark

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# Office Action Summary

Application N .

09/361,542

Applicant(s)

DOBROZSI, DOUGLAS JOSEPH

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of the Information Disclosure Statement and the Request for Reconsideration, received March 9, 2000, and June 22, 2000, respectively.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 13-23, 25, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 733 357 to Boltri *et al.* (hereinafter Boltri). Boltri discloses a topical formulation which is nebulizable by a mechanical pump, and contains colloidal silica (abstract). Boltri further teaches that the pharmaceutical formulation of his invention comprises colloidal silica in an amount from 2 to 15%, and a pharmaceutically active ingredient, as well as water and any other excipients conventionally used in pharmaceutical techniques (p 2, l 22-26). Further, Boltri teaches that the average diameter of the silica particles is between 7 and 40 nm, which reads on applicant's claim to less than 1 micron. Boltri also teaches that the composition can be used for topical, vaginal, nasal, and otological administration (p 3, l 15-17). This disclosure teaches the above claims, because these claims are drawn to a composition, and Boltri teaches the same components in the composition. Further, because Boltri teaches the same

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components in the composition, the ratios and viscosities claimed by applicant are considered inherent to the composition, and absent any evidence to the contrary, these characteristics render no patentable weight to the instant application. Therefore, the above listed claims are anticipated by the disclosure of Boltri *et al.*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boltri as applied to claims 1-11, 13-23, 25, and 29 above. Boltri is described above as disclosing a composition comprising colloidal silica (silicone dioxide), water, and other acceptable excipients. Boltri does not teach the specific inclusion of citric acid, however Boltri does teach the inclusion of pharmaceutical excipients in general, and it is the position of the examiner that one of ordinary skill in the art would use any well known excipient in the formulation disclosed by Boltri.

Further, Boltri does not disclose the method of coating the alimentary canal or treating the upper respiratory tract. However, based on the teachings that the formulation can be nebulized, it is the position of the examiner that one of ordinary skill in the art would take this to mean the composition could be inhaled through means well known in the pharmaceutical art. Therefore, one of ordinary skill in the art would have

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been motivated to use Boltri's formulation to treat the alimentary canal through inhalation therapy. One of ordinary skill in the art would expect the same results in this type of treatment as in treating the nasal and vaginal areas. Therefore, this invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam  
Patent Examiner  
Art Unit 1615  
August 29, 2000

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600